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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,773	09/18/2001	David A. Lightfoot	1268/2/2	8934
25297	7590	03/08/2004	EXAMINER	
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,773

Applicant(s)

LIGHTFOOT ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group VI, claims 38-42 in the response filed 16 December 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-37 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 16 December 2003.
3. This application contains claims 1-37 drawn to an invention nonelected without traverse in the response filed 16 December 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Specification

5. The first line of the specification, as amended in the Preliminary Amendment, filed 18 September 2001, must be amended to reflect the fact that the parental application has issued as US Patent 6,300,541.
6. The abstract of the disclosure is objected to because it contains information that is not directed to the elected invention. Correction is required. See MPEP § 608.01(b).
7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested -- A METHODS OF DETERMINING SOYBEAN SUDDEN DEATH SYNDROME RESISTANCE IN A SOYBEAN PLANT --.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
9. Claims 38-42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 38(a), the limitation "a low density inoculum" is relative and does not state the metes and bounds of the claimed invention.

At claim 38(c), the limitation "for a predetermined period of time" is indefinite and does not state the metes and bounds of the claimed invention.

At claim 38(f), it is unclear what the metes and bounds of "determining" is in relation to disease severity and/or infection severity and fungal colony forming units.

At claim 38(g), the multiple use of "and/or" renders the claim indefinite because it is unclear what the metes and bounds of this method step are. In addition, at line 5 of step (g) the limitation "to identify a correlation" renders the claim indefinite because it appears to be directed to a method of experimentation and not to producing a result from the method *per se*.

Claim 38, in general, is indefinite because the result of the method of identifying a correlation does not support the preamble directed to a method of determining soybean sudden death syndrome resistance, hence the metes and bounds of the claimed invention are unclear.

Claims 39 and 40 are also indefinite because they do not clarify the indefiniteness of claim 38 upon which they depend.

At claim 41(d) the metes and bounds of "characterizing resistance" is unclear because it is unclear how this is related to root infection severity.

Claim 42 is indefinite because it is unclear what the metes and bounds of "determining a level of resistance" are or how this method step is accomplished.

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 38-40 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method of determining soybean sudden death syndrome (SDS) resistance in a soybean plant in a greenhouse setting comprising inoculating soil with a low-density inoculum of *Fusarium solani*.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance for how to use the claimed method, wherein Applicant only teaches said method using a known SDS resistant soybean cultivar 'Forest', a known SDS susceptible soybean cultivar 'Essex' and progeny thereof. The art teaches that correlating field resistance for SDS using a greenhouse method requires a moderate inoculum rate of $4-5 \times 10^3$ spores/cm³ of soil, and that at low inoculum levels about 20% of field susceptible lines were identified as resistant (Njiti *et al* 2001, Crop Science 41:1726-1731, see especially pages 1729-1730). Hence, given the limited teachings of Applicant and the teachings of the art it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's

invention to screen through a myriad of soybean lines both susceptible and resistant to SDS using a low inoculum level in order to use the invention as claimed.

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 41 and 42 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Stephens *et al* 1993 (Crop Science 33:63-66).

Stephens discloses a method of characterizing resistance to soybean SDS in a soybean plant comprising isolating roots from a soybean plant infected by *Fusarium solani*, culturing the root on a culture plant including a restrictive growth medium containing tetracycline, determining “root infection severity by evaluating the colony forming units on said culture plate” and characterizing resistance to soybean SDS in said soybean plant and determining a level of resistance to SDS in the soybean plant (see page 64).

Stephens does not specifically teach statistically evaluating the number of colony forming units (CFUs) on the culture plate only a one to one correlation.

While it would have been *prima facie* obvious to one of ordinary skill to evaluate the number of CFUs on the culture plate, such a method step does not appear to teach a significant difference from the method taught by Stephens for characterizing resistance to soybean SDS in a soybean plant by culturing isolated root samples of a soybean, determining the presence of a SDS pathogenic *Fusarium solani* in a culture plant, and correlating the leaf symptoms of SDS with the presence of the fungus in the culture plant.

See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Conclusion

15. Claims 38-40 are free of the prior art, which neither teaches nor fairly suggests a method of determining soybean SDS in a soybean plant in a greenhouse setting comprising comparing disease severity and/or infection severity using fungal CFUs with genetic markers associated with soybean SDS resistance.
16. No claims are allowed.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "David H. Kruse", followed by the number "1638". The signature is stylized and cursive.

David H. Kruse, Ph.D.
5 March 2004